DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 19,2014

Baxter Healthcare Corporation
Mr. Gary Chumbimune
Manager
32650 N. Wilson Road
Round Lake, IL 60073

Re: K142600
Trade/Device Name: VIAL-MATE Reconstitution Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: October 22, 2014
Received: October 23, 2014

Dear Mr. Chumbimune:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K142600

Device Name
VIAL-MATE Reconstitution Device

Indications for Use *(Describe)*
To provide the pharmacist or health practitioner a means of connecting a standard 20 mm single dose drug vial to an I.V. solution container without mixing the vial contents with the diluent until immediately before administration of the reconstituted drug to the patient.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5 – 510(k) Summary K142600

September 12, 2014

OWNER:

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DEVICE NAME:

Trade Name:

VIAL-MATE Reconstitution Device

Table 1. VIAL-MATE Reconstitution Product Code

Code Number	Name
2B8071	VIAL-MATE Adaptor

Common name:

VIAL-MATE Reconstitution Device

Classification name:

Intravascular administration set (21 CFR 880.5440, Product Code LHI)

PREDICATE DEVICE:

Table 2. Predicate 510(k)s

Device	Company	Predicate 510(k)	Clearance date
VIAL-MATE Reconstitution Device	Baxter Healthcare	K973654	October 24, 1997

DEVICE DESCRIPTION:

The VIAL-MATE Reconstitution Device is intended for use by the pharmacist or health practitioner in the reconstitution and transfer of drugs into Baxter solution containers. The VIAL MATE Reconstitution Device provides a means of connecting a standard 20 mm single dose powdered drug vial to an I.V. solution container without mixing the vial contents with the diluents until immediately before reconstitution and administration of the drug to the patient. This device has been previously cleared under 510(k) premarket notification K973654 (cleared on October 24, 1997).

The basis for this premarket notification is a modification to the labeling of the product. This modification will update the label to clarify the description of the product and user instructions. Additionally, Baxter will update the product labeling to comply with Baxter's labeling standards and add the indications for use statement that was previously cleared for this device under 510(k) premarket notification K973654. The modification to the labeling does not impact the intended use or the fundamental scientific technology of the device. No new materials of construction are being introduced into this device as part of this update.

STATEMENT OF INTENDED USE:

To provide the pharmacist or health practitioner a means of connecting a standard 20 mm single dose drug vial to an I.V. solution container without mixing the vial contents with the diluent until immediately before administration of the reconstituted drug to the patient.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed VIAL-MATE Reconstitution Device is equivalent to Baxter's currently legally marketed VIAL-MATE Reconstitution Device cleared on October 24, 1997 (K973654). The modification to the labeling does not impact the intended use or the fundamental scientific technology of the device. No new materials of construction are being introduced into this device as part of this update. The intended use, the basic design, function and the materials for the proposed device are equivalent to the predicate device.

DISCUSSION OF NONCLINICAL TESTS:

Baxter Healthcare Corporation conducts risk analyses and design verification tests based on the result of these analyses. All test results meet their acceptance criteria, and support that the VIAL-MATE Reconstitution Device is appropriately designed for its intended use.

Performance Data:

The following bench tests were conducted to evaluate the functional performance of the VIAL-MATE Reconstitution Device:

- Seal flange to bag port adapter integrity
- Cannula to medication port integrity
- Septum to cannula hub integrity
- Septum to drug vial stopper integrity
- Port adapter removal force from the VIAFLEX container medication port
- Tamper evident seal integrity
- Vial gripper removal force from drug vial
- Flow through device to and from drug vial and VIAFLEX container
- Residual volume: Device vial and VIAFLEX container

All tests met the acceptance criteria.

Biocompatibility:

No new materials of construction are being introduced into this device as part of this Special 510(k) premarket submission. Biocompatibility assessment of the VIAL-MATE Reconstitution Device has been conducted based on ISO-10993-1, Biological Evaluation of Medical Devices for prolonged duration, external communicating device, indirect blood path, and Blue Book Memorandum G95-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing", as recommended in the IV administration sets guidance, "Guidance for Industry and FDA Staff: Intravascular Administration Sets Premarket Notification Submissions [510(k)]".

CONCLUSION:

The data from the non-clinical tests demonstrate that the proposed device is as safe and effective, and perform as well as the predicate device.